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EPAR summary for the public

Bondenza[1]

ibandronic acid

This is a summary of the European public assessment report (EPAR) for Bondenza. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Bondenza.

What is Bondenza?

Bondenza is a medicine that contains the active substance ibandronic acid. It is available as tablets (150 mg) and as a solution for injection in a prefilled syringe (3 mg).

What is Bondenza used for?

Bondenza is used to treat osteoporosis (a disease that makes bones fragile) in women who have been through the menopause and are at risk of developing bone fractures (breaks). Its effect in reducing the risk of spine fractures has been shown in studies, but its effect on the risk of fractures of the neck of the femur (the top of the thighbone) has not been established.

The medicine can only be obtained with a prescription.

How is Bondenza used?

Bondenza can be given either as a tablet or as an injection into a vein. If the tablet is used, the dose is one tablet every month, preferably on the same date each month. The tablet must always be taken after an overnight fast, one hour before any food or drink except for water, and with a full glass of plain water. (In areas with hard water, where tap water contains a lot of dissolved calcium, bottled water with a low mineral content may be used.) The patient must not lie down for one hour after taking the tablet. The dose by injection is 3 mg once every three months. Patients taking Bondenza should also take vitamin D and calcium supplements if they do not get enough from their diet.

[1] Previously known as Ibandronic Acid Roche.

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How does Bondenza work?

Osteoporosis happens when not enough new bone grows to replace the bone that is naturally broken down. Gradually, the bones become thin and fragile, and more likely to break. Osteoporosis is more common in women after the menopause, when the levels of the female hormone oestrogen fall, since oestrogen helps to keep bones healthy.

The active substance in Bondenza, ibandronic acid, is a bisphosphonate. It stops the action of the osteoclasts, the cells that are involved in breaking down the bone tissue. Blocking the action of these cells leads to less bone loss.

How has Bondenza been studied?

Bondenza has been studied in three main studies involving women with osteoporosis. The first study compared Bondenza 2.5-mg tablets taken once a day with placebo (a dummy treatment) in almost 3,000 women and looked at how many new spine fractures were seen in the patients over three years. The other two studies compared the 150-mg monthly tablets (1,609 patients) and the injections (1,395 patients) with the 2.5-mg once-daily tablets. The studies looked at the change in the density of the bones in the spine and the hip over two years.

The 2.5-mg once-daily tablets used in the studies are no longer authorised.

What benefit has Bondenza shown during the studies?

In the first study, daily treatment with Bondenza 2.5-mg tablets reduced the risk of new spine fractures by 62% in comparison with placebo. The other two studies showed that the 150-mg monthly tablets and the injections were more effective than the 2.5-mg once-daily tablets at increasing bone density in the spine and the hip. Over two years, bone density in the spine increased by 7% with the monthly tablets and by 6% with the injections, compared with 5% with the daily tablets. In the hip, bone density increased by 4% with the monthly tablets and by 3% with the injections, compared with 2% with the daily tablets.

What is the risk associated with Bondenza?

The most common side effects with Bondenza (seen in between 1 and 10 patients in 100) are arthralgia (joint pain) and influenza (flu)-like symptoms. For the full list of all side effects reported with Bondenza, see the package leaflet.

Bondenza must not be used in people who are hypersensitive (allergic) to ibandronic acid or any of the other ingredients. It must not be used in patients who have hypocalcaemia (low blood calcium levels). The tablets must not be used in patients who have abnormalities of the oesophagus or who cannot stand or sit upright for at least an hour.

Why has Bondenza been approved?

The CHMP decided that Bondenza's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Bondenza

The European Commission granted a marketing authorisation valid throughout the European Union for Ibandronic Acid Roche on 23 February 2004. The name of the medicine was changed to Bondenza on 18 August 2004.

The full EPAR for Bondenza can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Bondenza, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 12-2012.